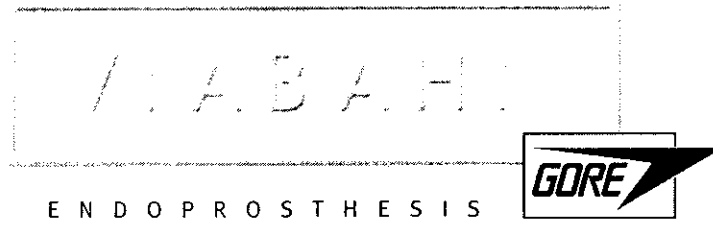


## INSTRUCTIONS FOR USE FOR:

---



**en**  
English

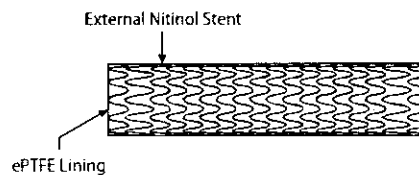
## INSTRUCTIONS FOR USE FOR GORE VIABAHN® ENDOPROSTHESIS

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

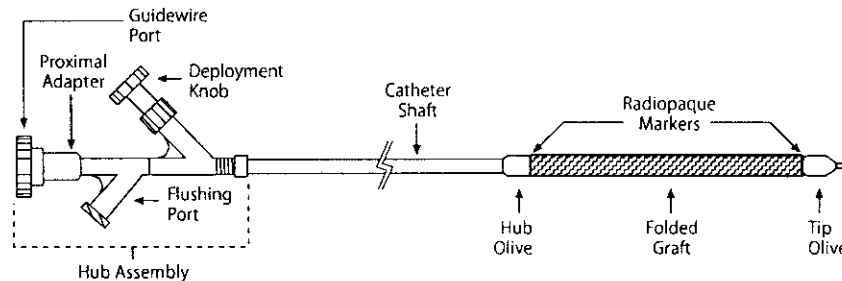
### DESCRIPTION

The GORE VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal graft consisting of an expanded polytetrafluoroethylene (ePTFE) lining with an external nitinol (NiTi = Nickel: Titanium) support extending along its entire length (Figure 1). The graft is compressed and attached to a dual lumen polyethylene delivery catheter available in working lengths of 75 cm and 110 cm (Figure 2). The larger central catheter lumen is used for flushing and guidewire introduction. The smaller lumen contains elements of the deployment mechanism. The delivery catheter is attached to a three-port clear plastic adapter (hub assembly) that includes a central port for guidewire introduction, a second port for system flushing, and a third port for the deployment system. To facilitate accurate graft placement, two radiopaque metallic bands are attached to the catheter shaft marking the ends of the compressed graft. The GORE VIABAHN® Endoprosthesis is supplied STERILE. The GORE VIABAHN® Endoprosthesis should not be resterilized.

**FIGURE 1: GORE VIABAHN® ENDOPROSTHESIS**



**FIGURE 2: GORE VIABAHN® ENDOPROSTHESIS DELIVERY SYSTEM**



### INTENDED USE/INDICATIONS

The GORE VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery lesions with reference vessel diameters ranging from 4.8 – 7.5 mm.

### CONTRAINDICATIONS

Non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system.

**TABLE 1: SIZING TABLE**

Device Sizing		Introducer Sheath Size (Fr)				Guidewire Diameter	Recommended Balloon Diameter for Device Touch-up (mm)	Deployment Direction
Labeled Device Diameter (mm)	Recommended Vessel Diameter <sup>1</sup> (mm)	2.5 cm Device Length <sup>2</sup>	5 cm Device Length <sup>2</sup>	10 cm Device Length <sup>2</sup>	15 cm Device Length <sup>2</sup>			
6	4.8 - 5.5	8	8	8	8	0.035" (0.889 mm)	6.0	Tip to hub
7	5.6 - 6.5	9	9	9	9	0.035" (0.889 mm)	7.0	Tip to hub
8	6.6 - 7.5	9	9	9	9	0.035" (0.889 mm)	8.0	Tip to hub

<sup>1</sup> Recommended graft compression within the vessel is approximately 5-20%.

<sup>2</sup> Labeled device lengths are nominal.

## METHOD

- Preparation of patients receiving the GORE VIABAHN® Endoprosthesis should include initiation of an appropriate dosage of oral antiplatelet medication prior to and following the procedure. Effective anticoagulation therapy should be maintained throughout the procedure and continued into the postoperative period, as deemed appropriate by the treating physician.
- **Prior to implantation of the GORE VIABAHN® Endoprosthesis, the physician should refer to the Sizing Table (Table 1) and read the Directions for Use.**
- When used in the treatment of stenotic or occlusive lesions, placement of the GORE VIABAHN® Endoprosthesis should immediately follow successful transluminal balloon angioplasty confirmed by angiography. The graft must be sized in accordance with the Sizing Table (Table 1) using accurate measurement techniques.
- Proper placement of the graft should be monitored and confirmed using fluoroscopy.
- Sterile precautions should be the same as for any device implant procedure.
- To ensure an optimal result, the graft **must be** dilated after deployment with an appropriately sized balloon (Table 1).

## WARNINGS

- W. L. Gore & Associates has insufficient clinical and experimental data upon which to base any conclusions regarding the effectiveness of the GORE VIABAHN® Endoprosthesis in applications other than the endovascular grafting of superficial femoral arteries or for the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.
- W. L. Gore & Associates has insufficient clinical and experimental data upon which to base any conclusions regarding the effectiveness of the GORE VIABAHN® Endoprosthesis in applications where the device is deployed within stents or stent grafts other than the GORE VIABAHN® Endoprosthesis. Other devices may interfere with the deployment of the GORE VIABAHN® Endoprosthesis resulting in deployment failure or other device malfunction.
- W. L. Gore & Associates has insufficient clinical and experimental data upon which to base any conclusions regarding the effectiveness of the GORE VIABAHN® Endoprosthesis in applications where the endoprosthesis may experience repeated and extreme flexion, such as across the popliteal fossa and the antecubital fossa. Clinical conditions such as excessive bending, tortuosity, and/or repeated and extreme flexion may result in compromised performance or failure of the endoprosthesis.
- Do not use the GORE VIABAHN® Endoprosthesis for the treatment of lesions that would not allow an operative salvage bypass procedure.
- Do not use the GORE VIABAHN® Endoprosthesis for the treatment of ostial lesions or lesions involving a major side branch that may be covered by the graft.
- Do not use in patients with less than one distal run-off vessel which has continuous patency to the ankle.
- Do not use in patients with a history of intolerance or adverse reaction to antiplatelet and/or anticoagulation therapies, bleeding diathesis, severe hypertension or renal failure.
- Special care should be taken to ensure that the appropriate size graft, compatible sheath and guidewire are selected prior to introduction. Native vessel dimensions must be accurately measured, not estimated.
- Do not cannulate or puncture the GORE VIABAHN® Endoprosthesis. Cannulating or puncturing the endoprosthesis may result in damage to the ePTFE graft and/or the external nitinol support, resulting in compromised performance or failure of the endoprosthesis.
- Do not cut the graft. The graft should only be placed and deployed using the supplied catheter system.
- Do not use a kinked introducer sheath. A kinked introducer sheath may increase the force necessary to deploy the graft and may cause a deployment failure or catheter breakage on removal.
- Do not attempt to deploy the graft or manipulate the delivery system without an appropriately sized guidewire (Table 1) and fluoroscopic guidance.
- Do not withdraw the GORE VIABAHN® Endoprosthesis back into the introducer sheath once the graft is fully introduced. Withdrawing the GORE VIABAHN® Endoprosthesis back into the sheath can cause damage to the graft, premature deployment, deployment failure, and/or catheter separation. If removal prior to deployment is necessary, withdraw the GORE VIABAHN® Endoprosthesis to a position close to but not into the introducer sheath. Both the GORE VIABAHN® Endoprosthesis and introducer sheath can then be removed in tandem. After removal, do not reuse the GORE VIABAHN® Endoprosthesis or introducer sheath.
- Inadvertent, partial, or failed deployment or migration of the graft may require surgical intervention.

## PRECAUTIONS

- The GORE VIABAHN® Endoprosthesis is designed for single use only.
- Do not use the GORE VIABAHN® Endoprosthesis if the sterile package is compromised or the GORE VIABAHN® Endoprosthesis is damaged.
- Do not use the GORE VIABAHN® Endoprosthesis after the labeled "use by" (expiration) date.
- Do not resterilize the GORE VIABAHN® Endoprosthesis.
- The GORE VIABAHN® Endoprosthesis should only be used by physicians trained in endovascular techniques. The implantation procedure should be performed only at facilities where surgical expertise is available.
- Follow the Directions for Use supplied with all accessories used in conjunction with the GORE VIABAHN® Endoprosthesis.
- Once deployment is started, repositioning the graft should not be attempted.
- Do not dilate the graft with a balloon longer than the labeled graft length (Table 1). Refer to Sizing Table (Table 1) for selection of appropriate balloon diameter.
- Do not attempt to withdraw or reposition a balloon catheter within the lumen of the deployed graft unless the balloon is completely deflated.
- Antiplatelet medication should be initiated prior to placement of the GORE VIABAHN® Endoprosthesis. Effective anticoagulation therapy should be maintained at a dosage deemed appropriate by the physician.
- Magnetic Resonance Imaging (MRI) compatibility of the GORE VIABAHN® Endoprosthesis was performed using a Signa 1.5 Tesla clinical imaging system. The results demonstrated that MRI using Fast Spin-echo, Spin-echo or Gradient echo sequencing should allow qualitative evaluation of patency within the graft, as well as proximal and distal to the graft. However, mild to moderate susceptibility to artifact and some signal intensity loss should be anticipated within the graft.
- No clinical events related to heating effects of GORE VIABAHN® Endoprostheses in the MRI environment have been reported. The effect of heating in the MRI environment for devices with fractured stent struts is not known.

## HAZARDS AND ADVERSE EVENTS

**Procedure Related:** As with all procedures that utilize techniques for introducing a catheter into a vessel, complications may be expected. These complications include, but are not limited to: access site infection; entry site bleeding and/or hematoma; vessel thrombosis, occlusion, pseudoaneurysm, and trauma to the vessel wall (including rupture or dissection); distal embolization; arteriovenous fistula formation; transient or permanent contrast induced renal failure; renal toxicity; sepsis; shock; radiation injury; myocardial infarction; fever; pain; malposition; malapposition; inflammation; and/or death.

**Device Related:** Complications and adverse events can occur when using any endovascular device. These complications include, but are not limited to: hematoma; stenosis, thrombosis or occlusion; distal embolism; side branch occlusion; vessel wall trauma and/or rupture; false aneurysm; infection; inflammation; fever and/or pain in the absence of infection; deployment failure; migration; and device failure.

Tables 8 and 9 reflect a complete description of adverse events observed in the clinical study of the GORE VIABAHN® Endoprosthesis.

## SUMMARY OF CLINICAL STUDIES

A total of 244 cases were treated at 25 U.S. investigational sites. The purpose of the study was to compare the safety and effectiveness of the GORE VIABAHN® Endoprosthesis to percutaneous transluminal angioplasty (PTA) in patients with chronic lower limb ischemia or chronic lifestyle altering claudication due to superficial femoral artery (SFA) atherosclerotic disease. A total of 241 patients or 244 cases (limbs) were treated in the study. Each site was permitted up to two training cases. A total of 47 training cases were performed; 197 cases were randomized with 100 assigned to PTA and 97 to the GORE VIABAHN® Device.

**Study Endpoints:** The primary endpoint was primary patency of the treated vessel at 12-months. Secondary endpoints included clinical success, the adverse event rate, as well as changes in the Ankle-Brachial Index (ABI), clinical success, and limb ischemia score. For purposes of analysis, patency of the treated vessel and technical success were redefined to more accurately reflect current clinical practices. The original endpoint definition of patency included the composite variables of technical success and treatment success of the treated vessel. Based on current clinical practices, the definition of patency was redefined as "no target revascularization procedure and no evidence of restenosis or occlusion within the originally treated vessel based on a centrally-read CFDU." Definitions are provided below Table 3. Endpoints were analyzed on an intent-to-treat (ITT) and per protocol (PP) basis.

**Patients Studied:** Eligible patients were candidates for PTA with de novo or restenotic atherosclerotic or occlusive lesion(s) of the superficial femoral artery causing either chronic lifestyle altering claudication or chronic lower limb ischemia. Stenotic or occlusive lesion(s) originating in the superficial femoral artery were ≤ 13 cm in length and ranging from 4.5 mm to 12 mm in diameter.

**Methods:** Patients eligible for the study, who had a percent diameter stenosis of < 50% following the initial PTA, were prospectively randomized to treatment with the GORE VIABAHN® Endoprosthesis or PTA. Baseline angiography was performed pre-PTA, post-PTA and post-procedure. Duplex Color Flow Doppler Ultrasound (CFDU) and clinical assessments were completed at discharge, and 1, 6 and 12 months post-procedure. For redefined patency of the target vessel, centrally read CFDU videotapes were utilized. Occlusion and restenosis were defined as no color flow or at least a focal doubling of peak systolic velocity (PSVR) respectively. PSVRs were calculated and videos with a PSVR greater than 2.0, as well as indeterminate cases, were identified for further review.

**Results:** The study was originally designed to enroll 415 patients. However, due to clinical study design and endpoint definitions, the Sponsor terminated the study prior to completion of enrollment. Technical success and primary patency were redefined, as described above, to be more clinically relevant. No safety issues were involved in the termination decision. Sites were instructed to follow their patients through the 1-year exam with optional follow-up at 2-years. Follow-up compliance through 12-months was 69% (69/100) for the PTA group and 79% (114/144) for the GORE VIABAHN® Device group.

**TABLE 2: SUMMARY OF PRE-PROCEDURE CHARACTERISTICS**

Variable	PTA (N = 100)	VIABAHN® Device All Cases (N = 144)	VIABAHN® Device Randomized Cases (N = 97)
Age (yrs), mean ± SD	66.9 ± 9.5	66.7 ± 10.1	67.2 ± 9.7
Males	70 (70.0%)	114 (79.2%)	80 (82.5%)
History of smoking	51 (51.0%)	73 (50.7%)	45 (46.4%)
History of MI	30 (30.0%)	38 (26.4%)	23 (23.7%)
History of diabetes mellitus	34 (34.0%)	49 (34.0%)	36 (37.1%)
ABI, mean ± SD	0.67 ± 0.18	0.73 ± 0.18	0.74 ± 0.17
RVD (mm), mean ± SD	5.6 ± 0.8	5.6 ± 0.6	5.6 ± 0.6
MLD (mm), mean ± SD	1.1 ± 1.0	1.2 ± 1.0	1.3 ± 1.0
Lesion length (cm), mean ± SD	6.7 ± 3.7	7.3 ± 3.6	7.3 ± 3.6
Percent diameter stenosis (%), mean ± SD	80.9 ± 17.1	77.7 ± 18.2	77.1 ± 17.5
Occlusion	29 (29.0%)	37 (25.7%)	20 (20.6%)

As shown in Table 3, there were no differences between the GORE VIABAHN® Endoprosthesis and PTA groups in the rates of primary patency of the treated vessel or technical success. The GORE VIABAHN® Device cases showed higher mean rates of treatment success and clinical success at 12-months. For redefined patency of the target vessel and technical success, the GORE VIABAHN® Device group had higher mean rates. A further breakdown of redefined patency by lesion length resulted in a benefit for GORE VIABAHN® Device cases with longer lesions (Table 5). Similarly, redefined technical success for GORE VIABAHN® Device cases with longer lesions (3-12 cm) was better than those in the PTA group (Table 6).

As shown in Table 4, the GORE VIABAHN® Device group demonstrated a trend towards greater clinical improvement at 6 and 12 months, as assessed with the clinical status score. There were no differences between groups in the mean change from baseline for the resting ABI and limb ischemia scores.

### Gender bias

A higher proportion of males (75%) than females (25%) were included in the trial, which is reflective of the distribution of the disease in the population. Females did not demonstrate as pronounced an advantage as males with respect to treatment success, clinical success, redefined patency and redefined technical success. The early and late adverse event rates for males and females were comparable. It was noted that GORE VIABAHN® Device male cases had a higher rate of early adverse events (major or minor) than PTA male cases (31.6% GORE VIABAHN® Endoprosthesis and 15.7% PTA). The difference is a result of a higher proportion of reports of minor pain in the leg, groin or back. The rates of adverse events for all other types of complications are comparable between groups for males.

**TABLE 3: SUMMARY OF EFFECTIVENESS OUTCOMES**

Effectiveness Measures	PTA	VIABAHN® Device All Cases	VIABAHN® Device Randomized Only
<b>ITT Population</b>	(N = 100)	(N = 144)	(N = 97)
<b>12-month Outcomes</b>			
Primary Patency	45%	51%	50%
Clinical Success	69%	84%	81%
Treatment Success	84%	94%	94%
Technical Success	61%	65%	59%
<b>Redefined</b>			
Patency at 12-months	40%	62%	65%
Technical Success	66%	94%	95%

**Primary patency of the target vessel:** A composite of treatment success, technical success and freedom from interrupted blood flow or revascularization to the treated vessel.

**Treatment success:** Completion of the assigned procedure without an additional recovery procedure or major adverse event, stenosis < 50% and patency by Color Flow Doppler ultrasound (CFDU).

**Technical success:** Treatment success and at 30 days no major adverse event and improvement in segmental limb pressure of 0.15.

**Clinical success:** Improvement of at least one category using the Rutherford Clinical Status Scale (1997). Cases with tissue loss must have improved by at least two categories and reach the level of claudication to be considered improved.

**Redefined technical success:** Successful completion of the assigned treatment and post-treatment angiographic results demonstrating less than 30% residual stenosis.

**Redefined patency of the target vessel:** No target vessel revascularization (TVR) procedure and no evidence of restenosis or occlusion within the originally treated vessel based on a centrally-read CFDU (occlusion and restenosis are defined as no color flow or at least a doubling of focal systolic velocity respectively).

**TABLE 4: SUMMARY OF CLINICAL OUTCOMES**

Clinical Measures	PTA	VIABAHN® Device All Cases	VIABAHN® Device Randomized Only
<b>ITT Population</b>	(N = 100)	(N = 144)	(N = 97)
<b>Clinical Status: Improved</b>			
1-month	89%	88%	87%
6-months	72%	84%	85%
12-months	75%	84%	82%
<b>Change in Limb Ischemia (means)</b>			
1-month	-1.73	-1.64	-1.61
6-months	-1.36	-1.55	-1.61
12-months	-1.45	-1.72	-1.62
<b>Change in ABI (means)</b>			
Discharge	.28	.25	.24
1-month	.29	.24	.22
6-months	.18	.22	.19
12-months	.22	.22	.19

**TABLE 5: SUMMARY OF REDEFINED TARGET VESSEL PATENCY  
BY LESION LENGTH-ITT POPULATION**

Variable (N = PTA / N = VIABAHN® Device All Cases / VIABAHN® Device Randomized Only)	PTA	VIABAHN® Device All Cases	VIABAHN® Device Randomized Only
All (100/144/97)	40%	62%	65%
Treatment Segment Length			
≤ 3 cm (21/23/19)	66%	67%	65%
3 - 6 cm (28/39/19)	39%	56%	64%
6 - 9 cm (21/37/29)	28%	66%	67%
9 - 12 cm (24/29/21)	38%	67%	68%
> 12 cm (6/16/9)	17%	54%	56%

**TABLE 6: SUMMARY OF REDEFINED TECHNICAL SUCCESS  
BY LESION LENGTH-ITT POPULATION**

Variable (N = PTA / N = VIABAHN® Device All Cases / VIABAHN® Device Randomized Only)	PTA	VIABAHN® Device All Cases	VIABAHN® Device Randomized Only
All (100/144/97)	66.0%	94.4%	94.8%
Treatment Segment Length			
< 3 cm (21/23/19)	90.5%	91.3%	94.7%
3 - 6 cm (28/39/19)	60.7%	94.9%	94.7%
6 - 9 cm (21/37/29)	71.4%	94.6%	93.1%
9 - 12 cm (24/29/21)	45.8%	93.1%	95.2%
> 12 cm (6/16/9)	66.7%	100.0%	100.0%

#### Adverse Events

There was a slight trend toward increased early adverse event rates in the GORE VIABAHN® Device groups compared with the control group; the difference in the early adverse event rates is small and does not raise safety concerns (Table 7). For complications especially pertinent to the procedure and device, the rates of occurrence of major amputation, bleeding events, vascular complications, and distal embolization were clinically indistinguishable. The rate of major device malfunction was low.

The rate of mortality was low in the study. One GORE VIABAHN® Device patient (0.7%) with significant co-morbidities died during the original hospitalization.

The rate of freedom from TVR was comparable between groups.

**TABLE 7: SUMMARY OF SAFETY**

Safety Measures ITT Population	PTA (N = 100)	VIABAHN® Device All Cases (N = 144)	VIABAHN® Device Randomized Only (N=97)
<b>Major Early AEs</b>			
Any Major AE	4.0%	7.6%	8.2%
Amputation	1.0%	0.0%	0.0%
Bleeding complications	0%	0.0%	0.0%
Vascular complications	0.0%	1.4%	1.0%
Distal embolization	1.0%	3.5%	4.1%
Device malfunction	0%	1.4%	2.1%
<b>Late AE (any major)</b>	13%	12.5%	8.2%
Mortality within 30-days	0%	0.7%	1.0%
TVR free rate at 12-months	79%	75%	80%

**Amputation:** Surgical removal of any portion of the involved leg, foot or toes.

**Bleeding complication:** Procedural blood loss of more than 1000 ml or post procedure related bleeding that occurs after the subjects left the OR resulting in need for transfusion.

**Vascular complication:** arterial rupture, artery injury, AV fistula, dissection, erosion through the vessel wall, false aneurysm, or puncture site bleeding.

**Distal embolization:** thrombus or embolism distal to the original treatment site.

**TVR:** target vessel revascularization.

Tables 8 and 9 reflect a complete description of adverse events observed in the clinical study of the GORE VIABAHN® Endoprosthesis.

**TABLE 8. MAJOR ADVERSE EVENTS THROUGH 12 MONTHS  
NUMBER (%)**

AE Category ITT Population	Early (≤ 30 days)			Late (> 30 days to 12-months)		
	PTA (N = 100)	GORE VIABAHN® Device All Cases (N=144)	GORE VIABAHN® Device Randomized Only (N=97)	PTA (N = 100)	GORE VIABAHN® Device All Cases (N=144)	GORE VIABAHN® Device Randomized Only (N=97)
Any Major Event*	4 (4.0)	11 (7.6)	8 (8.2)	13 (13.0)	18 (12.5)	8 (8.2)
Amputation	1 (1.0)	0 (0.0)	0 (0.0)	1 (1.0)	2 (1.4)	1 (1.0)
Bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bowel ischemia/obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contrast/medication reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac	3 (3.0)	1 (0.7)	1 (1.0)	8 (8.0)	11 (7.6)	4 (4.1)
Distal embolization	1 (1.0)	5 (3.5)	4 (4.1)	1 (1.0)	0 (0.0)	0 (0.0)
Hematoma	1 (1.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infection	0 (0.0)	1 (0.7)	1 (1.0)	1 (1.0)	1 (0.7)	0 (0.0)
Neurovascular	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain (leg/groin/back)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	1 (0.7)	1 (1.0)
Paraparesis/paraplegia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Post implant syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary	0 (0.0)	1 (0.7)	1 (1.0)	1 (1.0)	0 (0.0)	0 (0.0)
Renal failure	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	2 (2.1)
Stroke/TIA	0 (0.0)	1 (0.7)	1 (1.0)	1 (1.0)	4 (2.8)	1 (1.0)
Vascular	0 (0.0)	2 (1.4)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Deep venous thrombosis	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)

\* Any Major Event includes the following: a) requires therapy, minor hospitalization (< 48 hours), b) requires major therapy, unplanned increase in level of care, prolonged hospitalization, c) permanent adverse sequelae or d) death. Cases may have had multiple events.

**TABLE 9: MINOR ADVERSE EVENTS THROUGH 12 MONTHS  
NUMBER (%)**

AE Category ITT Population	Early (≤ 30 days)			Late (> 30 days to 12-months)		
	PTA (N = 100)	GORE VIABAHN® Device All Cases (N=144)	GORE VIABAHN® Device Randomized Only (N=97)	PTA (N = 100)	GORE VIABAHN® Device All Cases (N=144)	GORE VIABAHN® Device Randomized Only (N=97)
Any Minor Event*	17 (17.0)	33 (22.9)	24 (24.7)	2 (2.0)	6 (4.7)	5 (5.2)
Amputation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bowel ischemia/obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contrast/medication reaction	4 (4.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac	2 (2.0)	4 (2.8)	3 (3.1)	0 (0.0)	1 (0.7)	1 (1.0)
Distal embolization	2 (2.0)	6 (4.2)	4 (4.1)	0 (0.0)	1 (0.7)	1 (1.0)
Hematoma	7 (7.0)	13 (9.0)	12 (12.4)	0 (0.0)	1 (0.7)	1 (1.0)
Infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurovascular	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain (leg/groin/back)	3 (3.0)	14 (9.7)	10 (10.3)	3 (3.0)	3 (2.1)	1 (1.0)
Paraparesis/paraplegia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Post implant syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal failure	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stroke/TIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular	3 (3.0)	7 (4.9)	6 (6.2)	0 (0.0)	1 (0.7)	1 (1.0)
Other	1 (1.0)	4 (2.8)	3 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)

\* A Minor Adverse Event is an adverse event that does not meet the definition of a Major Adverse Event. See Table 8.

\*\* Other includes the following: VIABAHN® Device: Thigh pain; focal slight intimal defect distal to the stent graft ; nausea; generalized pruritus without rash. PTA: After fem stop was applied to right groin, patient experienced vasovagal reaction without hypotension.

#### PATIENT DEATH SUMMARY

One GORE VIABAHN® Device subject died 16 days after the procedure. This subject had significant co-morbidities and sepsis was reported as the cause of death.

One GORE VIABAHN® Device subject and three PTA subjects died more than 30 days but less than 12 months post-procedure. The GORE VIABAHN® Device patient died approximately 6 months post-procedure. The exact date and cause are unknown. Two PTA subjects died due to a myocardial infarction (MI) and the third due to a pulmonary embolus and MI.

In the second year of follow-up, two GORE VIABAHN® Device subjects died. One died with secondary heart failure due to chemotherapy and radiation therapy for lung cancer. The other subject had a history of coronary artery disease (CAD), congestive heart failure (CHF), MI and diabetes. This subject developed gangrene and had an above the knee amputation; the patient expired several days later.

#### OBSERVED DEVICE MALFUNCTIONS

Device malfunctions were observed in eight cases (10 incidents). Those involving the delivery catheter included four attributed to difficulty removing the delivery device and two catheter tip breakage. One involved a deployment failure or malfunctioning stent, one introduction with device kinking, one balloon catheter rupture during post-dilation and one guidewire tip breakage.

#### SELECTED PUBLICATIONS

Additional clinical experiences using the GORE VIABAHN® Endoprosthesis in the superficial femoral artery have been reported in the literature. These reports provide additional long-term performance information regarding the safety and effectiveness of the device for the superficial femoral artery indication. Selections from that literature are included below (See Tables 10 and 11) and the literature citations are provided at the end of this section. These studies report patency rates comparable to those reported in this PMA. Technical success that was reported was 100%. Adverse events reported in the literature were minor and occurred acutely. The rate of distal embolization reported in the clinical trial in Table 7 is comparable to the range of rates reported in the literature.

**TABLE 10 – SUMMARY OF EFFECTIVENESS (PATENCY) FROM SELECTED GORE VIABAHN® ENDOPROSTHESIS LITERATURE**

Author Yr. Tx. Seg.	N (Limbs) / Avg. Length (cm)	Primary Patency (years)						Patency Definition
		0.5	1	2	3	4	5	
Bleyn 2004 SFA	67 / 14.3	84%	82%	73%	68%	54%	47%	Patent by duplex ultrasound
Saxon 2004 SFA	42 / > 10	90%	86%	79%	79%	70%	—	No occlusion and absence of 50% restenosis as determined by duplex ultrasound (PSVR < 2.0)
Bauermeister 2001 SFA	35 / 22	79%	73%	—	—	—	—	No occlusion and absence of 50% restenosis as determined by duplex ultrasound
Lammer 2000 SFA	80 / 13.8	90%	79%	—	—	—	—	No occlusion and absence of 50% restenosis as determined by duplex ultrasound (PSVR < 2.5)
Avg.	224 / 15.0	86%	80%	76%	73.5%			

**TABLE 11 - SUMMARY OF SAFETY (ADVERSE EVENTS) FROM SELECTED GORE VIABAHN® ENDOPROSTHESIS LITERATURE**

Author Yr. Tx. Seg*	N (Limbs) / Avg. Length (cm)	Distal Embolization	Hematoma	Post-Implant Syndrome <sup>1</sup>	Acute Thrombosis	Infection	Conversion	Amputation	Death
Tarantini 2004 SFA	28 / 29	NR**	NR	NR	NR	NR	NR	11% <sup>1</sup>	0%
Saxon 2004 SFA	42 / > 10	7% <sup>2</sup> (minor) 7% (req tx.)	NR	15% <sup>1</sup>	5%	NR	NR	NR	NR
Bleyn 2004 / 2002 SFA	67 / 14.3	27% <sup>4</sup>	9% <sup>5</sup>	NR	— <sup>4</sup>	NR	NR	1%	1% <sup>6</sup>
Jahnke 2003 SFA Fem Pop	52 / 8.5	7.7% <sup>2</sup>	13.5%	5.8% <sup>4</sup>	2%	NR	0% in first 30 days	NR	NR
Bauermeister 2001 SFA	35 / 22	NR	NR	NR	3%	NR	NR	NR	NR
Lammer 2000 SFA	80 / 13.8	3%	2%	NR	4%	0%	0%	0%	0%
TOTAL	304 / 16.2								

\* Treated Segment. SFA refers to superficial femoral artery; Fem Pop refers to Femoropopliteal artery.

\*\* NR = None Reported for a particular adverse event, although adverse events are discussed within the publication. Fields with -- reflect papers without any discussion of adverse events generally.

<sup>1</sup> "There were three amputations: one for graft failure and two for progressive gangrene despite graft patency."

<sup>2</sup> "Angiography detectable embolization was seen in 14% (6/42) of treated limbs in our series. However 3 of the these cases were felt to be clinically insignificant small vessel occlusions, they caused no adverse event clinical sequelae and one resolved spontaneously. Clinically significant embolization occurred in 7% (3/42) of treated limbs. The majority of embolizations were detected in patients who had an endograft placed following catheter-directed thrombolysis for acute arterial occlusions. Further lysis or suction embolectomy has been universally successful in sever/symptomatic cases."

<sup>3</sup> Post Implantation Syndrome is described as localized thigh pain occurring for one to two weeks following device placement and appears to be related to excessive oversizing of touch-up ballooning of the VIABAHN Endoprosthesis. "The pain started immediately after placement and lasted 1 to 2 weeks, occasionally requiring narcotic analgesia..." "We suspect the pain is because of over-expansion of the vessel by the endoprosthesis at initial dilation. We now dilate the device to the size of the normal vessel... Since we have stopped substantially over-dilating the vessel, pain postprocedure has been much less of an issue."

<sup>4</sup> Distal embolization and acute thrombosis are reported together. "Peripheral emboli or postoperative thrombosis was diagnosed in 18 (26.9%) patients, but only 1 was resistant to immediate thrombolysis." "the Hemobahn endoprosthesis was implanted percutaneously without systemic heparinization"

<sup>5</sup> "Conservatively treated hematoma"

<sup>6</sup> "death due to a retroperitoneal hematoma in combination with poor cardiopulmonary function."

- <sup>7</sup> "all successfully treated by aspiration thrombectomy and/or short-term local fibrinolysis;"... "All cases of distal embolization occurred in patients who initially presented with total occlusions;"... "were without clinical sequelae"
- <sup>8</sup> "minor groin hematoma in seven patients;"... "were without clinical sequelae"

## LITERATURE CITATIONS FOR SELECTED PUBLICATIONS

Tarantini F.A., et al., Use of Expanded Polytetrafluoroethylene Covered Endoprosthesis for the Treatment of Infrapopliteal Arterial Occlusive Disease. Abstract presented at the Eastern Vascular Society (EVS) 18th Annual Meeting, April 29-May 2, 2004, Philadelphia, PA. page 62.

Bleyn J, Schol F, Vanhandenhove I, Vercaeren P, Marien C. in Controversies and Updates in Vascular and Cardiac Surgery, Chapter 14. Edizioni Minerva Medica, Torino, Italy 2004.

Bleyn J, Goverde P, Hemobahn in Superficial Femoral Artery Occlusive Disease: Long-term Results. Abstract presented at the 15th Annual International Congress. Feb. 10-14, 2002, Scottsdale, AZ. page X-7.

Saxon RR, Coffman, MJ, Gooding JM, and Ponc DJ. Endograft Use in the Femoral and Popliteal Arteries. Techniques in Vascular and Interventional Radiology 2004; 7(1): 6-15.

Jahnke, T et al., Hemobahn Stent-Grafts for Treatment of Femoropopliteal Arterial Obstructions: Midterm Results of a Prospective Trial" Journal of Vascular and Interventional Radiology 2003; 14:41-51

Bauermeister G. Endovascular stent-grafting in the treatment of superficial femoral artery occlusive disease. Journal of Endovascular Therapy 2001; 8:315-320.

Lammer J, Dake MD, Bely J, et al. Peripheral Arterial Obstruction: Prospective Study of Treatment with a Transluminally Placed Self-Expanding Stent Graft. Radiology 2000; 27:95-104.

## CONCLUSIONS DRAWN FROM THE STUDIES

The preclinical studies indicate that the GORE VIABAHN® Endoprosthesis meets or exceeds safety and performance specifications.

The randomized clinical trial results, and information drawn from the published literature, provide reasonable assurance that the GORE VIABAHN® Endoprosthesis is safe and effective when used in accordance with its labeling. Multicenter, randomized clinical study results demonstrated that the GORE VIABAHN® Device when compared to PTA resulted in higher rates of treatment success, technical success, and 12-month patency as defined by current clinical standards. Likewise, the GORE VIABAHN® Device cases demonstrated a trend towards greater improvement for clinical success and clinical status scores. Other primary efficacy parameters were comparable between the GORE VIABAHN® Endoprosthesis and PTA groups. Multicenter clinical data show that the rates of adverse events for the GORE VIABAHN® Endoprosthesis group were comparable to the PTA group.

The preclinical testing information and the randomized clinical trial results provide valid scientific evidence and reasonable assurance that the GORE VIABAHN® Endoprosthesis is safe and effective when used in accordance with its labeling.

## DIRECTIONS FOR USE

### MATERIALS REQUIRED FOR IMPLANTATION

- GORE VIABAHN® Endoprosthesis
- Marker guidewire or catheter (for calibrated measurement reference)
- Syringe with attached stopcock filled with heparinized saline
- Introducer sheath of appropriate size (Table 1)
- Stiff guidewire: diameter must be  $\leq 0.035"$  (0.889 mm) for device diameters of 6, 7, and 8 mm
- Guidewire length should be at least twice the length of the GORE VIABAHN® Endoprosthesis delivery catheter
- Appropriate angioplasty balloon catheters and accessories (Table 1)
- Appropriate diagnostic catheters and accessories

### Treatment of Vessel Obstruction

#### A. Access

1. Using appropriate local anesthesia, access is achieved using the appropriate vessel. When possible, a percutaneous Seldinger technique is preferred. A cutdown may be performed when indicated.
2. Using standard technique, insert the appropriately sized angiographic vascular introducer sheath into the vessel.

#### B. Imaging and Measurement

1. To achieve accurate measurement and ensure precise sizing and placement of the graft, use image-centered, magnified-view contrast angiography, including a marker guidewire or catheter.

**C. Percutaneous Transluminal Angioplasty (PTA) (If treating stenotic or occlusive lesions)**

1. Refer to manufacturer's Directions for Use.
2. Inflate the angioplasty balloon to its nominal pressure according to manufacturer's Directions for Use. Ensure full expansion of the balloon within the lesion. **Note:** Carefully mark the margins of the angioplasty treatment segment in order to ensure complete coverage with the graft.
3. Following deflation of the angioplasty balloon, evaluate the results angiographically. For reference, measure the native vessel diameter, lesion length, and residual percent stenosis.

**D. Sizing and Selection of the GORE VIABAHN® Endoprosthesis**

1. Prior to Opening the Sterile Package. Check that the diameter and length of the graft as well as the delivery catheter length are correct before removing from the packaging.
  - a. In selecting the appropriate size graft, a careful assessment of the vessel is necessary. In general, to assure adequate anchoring, the diameter of the graft should be approximately 5-20% larger than the healthy vessel diameter immediately proximal and distal to the lesion (Table 1).
  - b. The graft lengths of the GORE VIABAHN® Endoprosthesis listed in Table 1 are nominal. It is, therefore, important that the graft overlap the native vessel at least 1 cm beyond the proximal and distal margins of the lesion when treating stenotic or occlusive lesions.
  - c. Verify that there is sufficient catheter length to access the treatment site.
2. When overlapping (telescoping) multiple devices, the following are suggested:
  - Balloon touch-up (post-dilatation) should be performed on the first device prior to placing the second device.
  - To ensure proper seating, at least 1 cm of overlap between devices is suggested.
  - Overlapping devices should not differ by more than 1 mm in diameter.
  - If unequal device diameters are used, the smaller device should be placed first and then the larger device should be placed inside of the smaller device.

**E. Preparation of the GORE VIABAHN® Endoprosthesis**

1. Opening the Sterile Package. Carefully inspect the packaging for damage to the sterile barrier. Do not use the GORE VIABAHN® Endoprosthesis after the "use by" (expiration) date. Peel back the outer pouch and remove the sterile inner pouch and tray containing the GORE VIABAHN® Endoprosthesis. Beginning at one corner, peel back the edge of the inner pouch and gently remove the GORE VIABAHN® Endoprosthesis.
2. Inspection Prior to Use.
  - Prior to using the GORE VIABAHN® Endoprosthesis, all materials and equipment to be used for the procedure should be carefully examined for bends, kinks, or other damage.
  - Do not use any defective equipment.
  - Do not use the GORE VIABAHN® Endoprosthesis if the sterile package is compromised or the GORE VIABAHN® Endoprosthesis is damaged.
3. Preparation of the GORE VIABAHN® Endoprosthesis delivery catheter.
  - a. Tighten the guidewire port "O"-ring. Flush the delivery catheter by attaching a syringe of heparinized saline and stopcock to the flushing port on the catheter adapter (Figure 1). Continue flushing until a steady stream of fluid exits the tip of the catheter.
  - b. After flushing the catheter, close the stopcock, remove the syringe, and loosen the guidewire port "O"-ring.

**F. Introduction and Positioning of the GORE VIABAHN® Endoprosthesis**

1. **Select the compatible size introducer sheath from Table 1.**
2. Ensure the stiff guidewire is = 0.035" (0.889 mm) for 6, 7 and 8 mm device diameters and has a length at least twice that of the delivery catheter.
3. Be sure to remove the balloon catheter while maintaining the position of the guidewire beyond the target lesion.
4. With the delivery catheter as straight as possible, insert the guidewire into the tip of the delivery catheter while supporting the delivery catheter and the compressed graft. Carefully advance the endoprosthesis in small increments (approximately 0.5 cm) over the guidewire, through the hemostasis valve and introducer sheath, and into the access vessel. **Note:** If excessive resistance is felt as the GORE VIABAHN® Endoprosthesis is introduced through the hemostasis valve, remove and inspect the delivery system for damage. Do not reuse the GORE VIABAHN® Endoprosthesis if damaged. Ensure a compatible introducer sheath size (Table 1), and that the introducer sheath is free of kinks.
5. Using fluoroscopic guidance, advance the delivery catheter over the guidewire via the angiographic sheath. Advance cautiously, especially if resistance is felt.
6. Position the GORE VIABAHN® Endoprosthesis across the target lesion using the radiopaque hub and tip markers on the catheter. These markers identify the proximal and distal ends of the graft, respectively. **Note:** If PTA is performed, the graft length should cover the entire vessel segment treated with balloon angioplasty. For treatment of stenotic or occlusive lesions, the graft should extend at least 1 cm proximal and distal to the margins of the lesion.


7. Once the optimal position is verified fluoroscopically, the graft is ready to be deployed.  
 Note: Should it become necessary to remove the GORE VIABAHN® Endoprosthesis from the vessel prior to deployment, do not withdraw the GORE VIABAHN® Endoprosthesis back into the introducer sheath after the graft is fully introduced. To remove the GORE VIABAHN® Endoprosthesis prior to deployment, the GORE VIABAHN® Endoprosthesis can be withdrawn to a position close to but not into the introducer sheath. Both the GORE VIABAHN® Endoprosthesis and introducer sheath can then be removed in tandem. After removal, neither the GORE VIABAHN® Endoprosthesis nor the introducer sheath should be reused.


#### G. Deployment of the GORE VIABAHN® Endoprosthesis

1. Stabilize the delivery catheter at the hemostasis valve of the introducer sheath. It is also important to stabilize the delivery catheter and introducer sheath relative to the patient. This will minimize catheter movement during deployment and ensure accurate graft positioning.
2. Untwist the screw-connector at the base of the deployment knob. While keeping the extracorporeal segment of the catheter as straight as possible, slowly pull the deployment knob away from the adapter. **Deployment of the graft will occur from the tip of the delivery catheter toward the hub for the 6, 7 and 8 mm diameter devices.** If deployed as instructed, the graft should not appreciably shorten.  
**Note: Once deployment has started, repositioning of the graft should not be attempted.**
3. While maintaining the position of the guidewire across the treated lesion, carefully withdraw the delivery catheter through the lumen of the graft and remove it via the introducer sheath. Moderate resistance may be felt when the distal tips exit through the hemostasis valve of the introducer sheath. Note: If, during catheter removal, the tip olive catches on the leading edge of the graft, a slight "back and forth" motion of the catheter may aid in release. Excessive or abrupt force during catheter removal may damage the graft or cause separation at the catheter tip.
4. After deployment, the graft must be smoothed and seated against the vessel wall by inflating an angioplasty balloon within it. Touch-up balloon diameter should be selected according to Table 1. It should be inflated to the desired diameter along the entire length of the graft. If the graft length exceeds that of the balloon, multiple inflations may be needed. After the balloon is inflated throughout the graft, attention is required to ensure complete deflation of the balloon prior to cautious removal of the balloon catheter to prevent graft displacement. **Do not extend balloon dilatation beyond the ends of the device and into healthy vessel.**
5. Using contrast angiography, evaluate the treated segment prior to completing the procedure. Further balloon inflations may be necessary if residual graft folds or invaginations are visualized angiographically. A final angiographic run to evaluate vessel patency to the foot is recommended.
6. When clinically appropriate, remove the introducer sheath and achieve hemostasis of the puncture site.


#### DEFINITIONS

 Use By

 Attention, See Instructions for Use

 Do Not Re-Use

 Catalogue Number


 Batch Code


 **STERILE**

Contents sterile unless package has been opened or damaged.


 **STERILE EO**

Contents sterile unless enclosed package has been opened or damaged. Sterilized by ethylene oxide.

 Catheter Length

 Device Deploys from Tip to Hub

 Diameter

 Guidewire Compatibility

 Vessel Diameter



AJ0108-EN1



**W. L. Gore & Associates, Inc.**  
Flagstaff, Arizona 86004  
**USA**

**[www.goremedical.com](http://www.goremedical.com)**

Order Information: Tel.: 928 / 526-3030  
Tel.: 800 / 528-8763

Technical Information: Tel.: 928 / 779-2771  
Tel.: 800 / 437-8181

MADE IN USA.

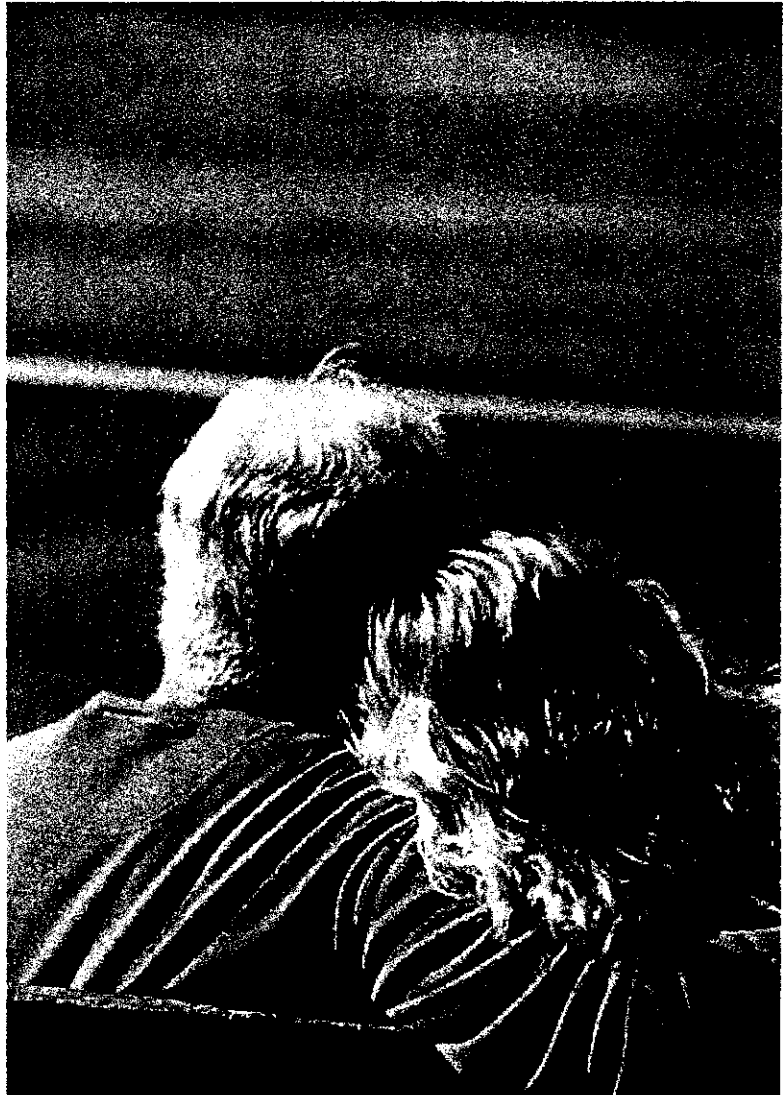
GORE, VIABAHN®, and designs are trademarks of W. L. Gore & Associates.

Signa is a trademark of General Electric.

© 2005 W. L. Gore & Associates, Inc.

Printed on recyclable paper

JUNE 2005



*Patient Information*

VIA BAHN

ENDOPROSTHESIS



## *Table of Contents*

Introduction .....	3
What is Peripheral Vascular Disease? .....	5
What Are Some of the Symptoms of Peripheral Vascular Disease? .....	7
What Causes Peripheral Vascular Disease? .....	8
How Do Doctors Treat Peripheral Vascular Disease? .....	9
What is the GORE VIABAHN® Endoprosthesis? .....	11
How is the GORE VIABAHN® Endoprosthesis Implanted? .....	13
What Are the Risks of the GORE VIABAHN® Endoprosthesis? .....	15
What Follow-Up Examinations Should I Have? .....	17
When Should I Call My Doctor? .....	17
Glossary of Medical Terms .....	18
Where Can I Get More Information? .....	20
Questions for My Doctor .....	21

*This brochure has been provided as a courtesy from Gore & Associates.*

*It is designed to provide helpful information about risk factors*

*and common symptoms associated with peripheral artery*

*disease. Additionally, it provides information about a*

*new, minimally-invasive method for treating it.*

*We hope this information will be helpful to*

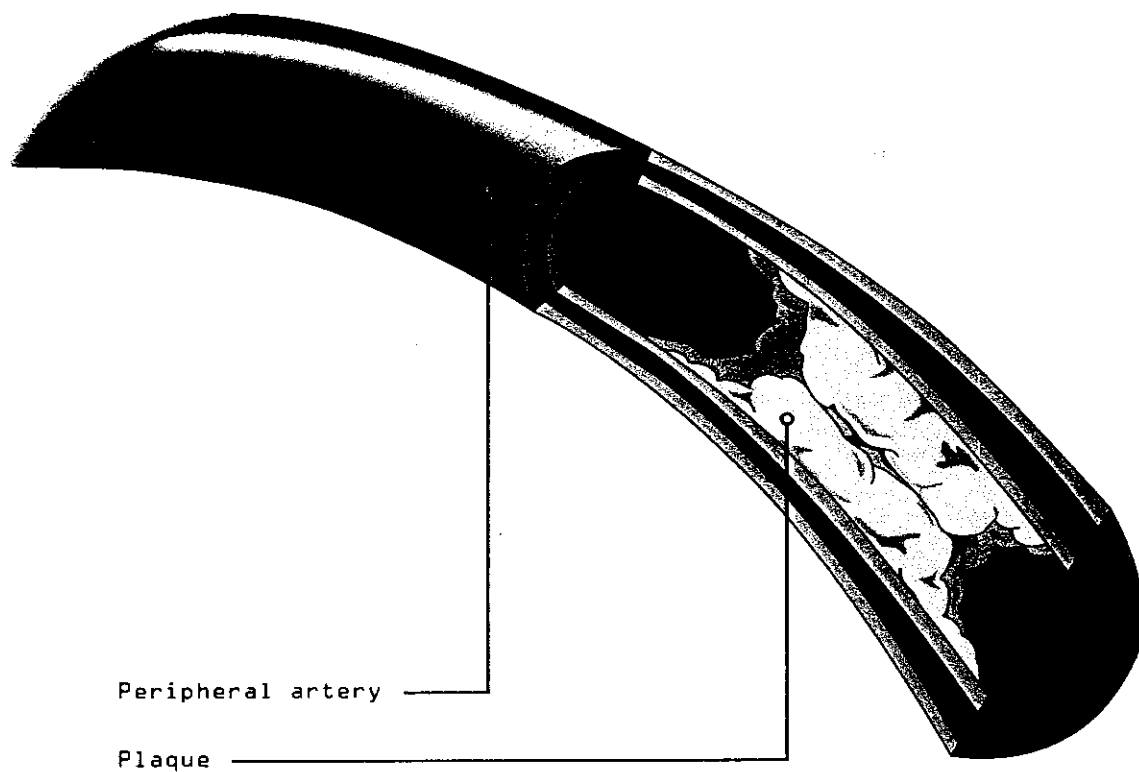
*you and your family.*

## *Introduction*

In the U.S. alone, approximately 8-12 million people suffer from some form of peripheral vascular disease (PVD). Peripheral vascular disease is caused by the buildup of plaque inside the arteries in the lower limbs, resulting in decreased blood flow. This brochure describes peripheral vascular disease and some of the available treatment options. One new treatment option is **endovascular repair** using an **endovascular graft**.

For your convenience, we have included a **Glossary of Medical Terms** on page 18 and space in this brochure on page 21 to jot down questions to discuss with your doctor. Words that are **bold** throughout the text can be found in the Glossary of Medical Terms.

This brochure is an informational and referral guide only, and is not intended to diagnose a medical condition. As with any surgery or medical procedure, the best resource for information and advice is your doctor. For additional information from Gore & Associates, please call 1-800-528-8763, or visit our website at [goremedical.com](http://goremedical.com).



**Atherosclerosis** — the build-up of plaque and fatty acids in the artery over time.

Figure 1

## *What is Peripheral Vascular Disease?*

Vascular disease involves the buildup of plaque and fatty substances on the inner lining of arteries, a process called **atherosclerosis** (see Figure 1). This process commonly occurs in arteries throughout the body over time. The presence of **atherosclerosis** in **peripheral arteries** is usually referred to as peripheral vascular disease. The term **stenosis** describes a **lesion** in the artery in which blood flow is partially blocked; a lesion in which the artery is completely blocked is called an **occlusion**.

The most common locations of **PVD** (peripheral vascular disease) are in the legs, arms, neck, and kidneys. During early stages of **PVD**, symptoms are usually rare; however, as the buildup of plaque progresses, it blocks the flow of blood through the artery to tissues and organs. The symptoms resulting from **PVD** depend on the location and extent of the disease. Over time, symptoms may stabilize or may become worse, requiring intervention to open the blockage.

The information in this brochure will focus on the treatment of **PVD** in the **superficial femoral arteries (SFA)**, blood vessels that deliver blood to the legs.



## *What Are Some of the Symptoms of Peripheral Vascular Disease?*

Many people do not experience any symptoms of peripheral vascular disease (PVD). In many of these cases, treatment is unnecessary. However, as symptoms increase in severity, action may be required. Depending on the location of the disease, one or more of the following symptoms may be present:

- Claudication (dull pain in the buttocks, thighs, calves, or feet following exercise or walking)
- Numbness or tingling in the leg, foot, or toes
- Changes in skin color (i.e., paleness or a bluish color) in the leg, foot, or toes
- Absence of a pulse
- Ulcers (sores) on the foot or toes that will not heal
- Gangrene
- Hypertension (uncontrolled high blood pressure)
- Kidney failure

PVD is usually identified as a result of the development of one or more of the symptoms mentioned above. If your physician suspects the presence of PVD, a medical test such as an **angiogram** or **ultrasound** is usually conducted to confirm it or rule it out.

## *What Causes Peripheral Vascular Disease?*

Over time, the accumulation of fatty substances on the vessel wall, combined with inflammation of the vessel wall, limits blood flow. When the blood flow becomes severely limited, the muscles surrounding the artery do not receive enough oxygen, and you feel pain. The cause of this process is not completely understood, but many factors have been identified that increase the likelihood of PVD.

Risk factors for developing PVD include:

- heredity (family history)
- smoking
- diabetes
- heart disease
- obesity
- high blood pressure
- high cholesterol

Most doctors will advise simple preventative measures such as keeping your blood pressure under control, stopping smoking, exercising regularly, and reducing cholesterol in your diet. These lifestyle changes could also aid in preventing further problems in the future.

## *How Do Doctors Treat Peripheral Vascular Disease?*

The amount and location of the peripheral vascular disease, and your general health, will determine how you should be treated. When the symptoms are mild, your doctor may only recommend periodic check-ups. However, more serious symptoms may require treatment. Several options are available if your doctor feels treatment is necessary:

- **Risk Factor Modification:** Before performing a procedure, your doctor may recommend changes in your lifestyle to treat your PVD, including decreasing the amount of fat and cholesterol in your diet, stopping smoking, and exercising regularly.
- **Medical Management:** Your physician may also prescribe medicine to improve the blood flow in your arteries or to lower the cholesterol present in your blood.
- **Bypass Surgery:** If lifestyle modification and medical management fail to remove the symptoms, direct treatment may be necessary. Your physician may choose to surgically bypass the diseased artery with either a man-made graft or one of your own veins. Bypass surgery has been performed for many years with well-established, long-term results.
- **Interventional Treatment:** Many of the potential complications that could occur with traditional **open surgery** may be avoided by a more recently available technique called interventional treatment. Interventional treatment does not require open surgery. By using small wires and X-rays, doctors can work inside the blocked artery. This procedure is performed through a small hole in an artery in the groin, and may include **angioplasty** (opening the blockage by inflating a small balloon in the diseased area), or **stenting** (placement of a small, metallic device in the diseased area to hold the artery open).

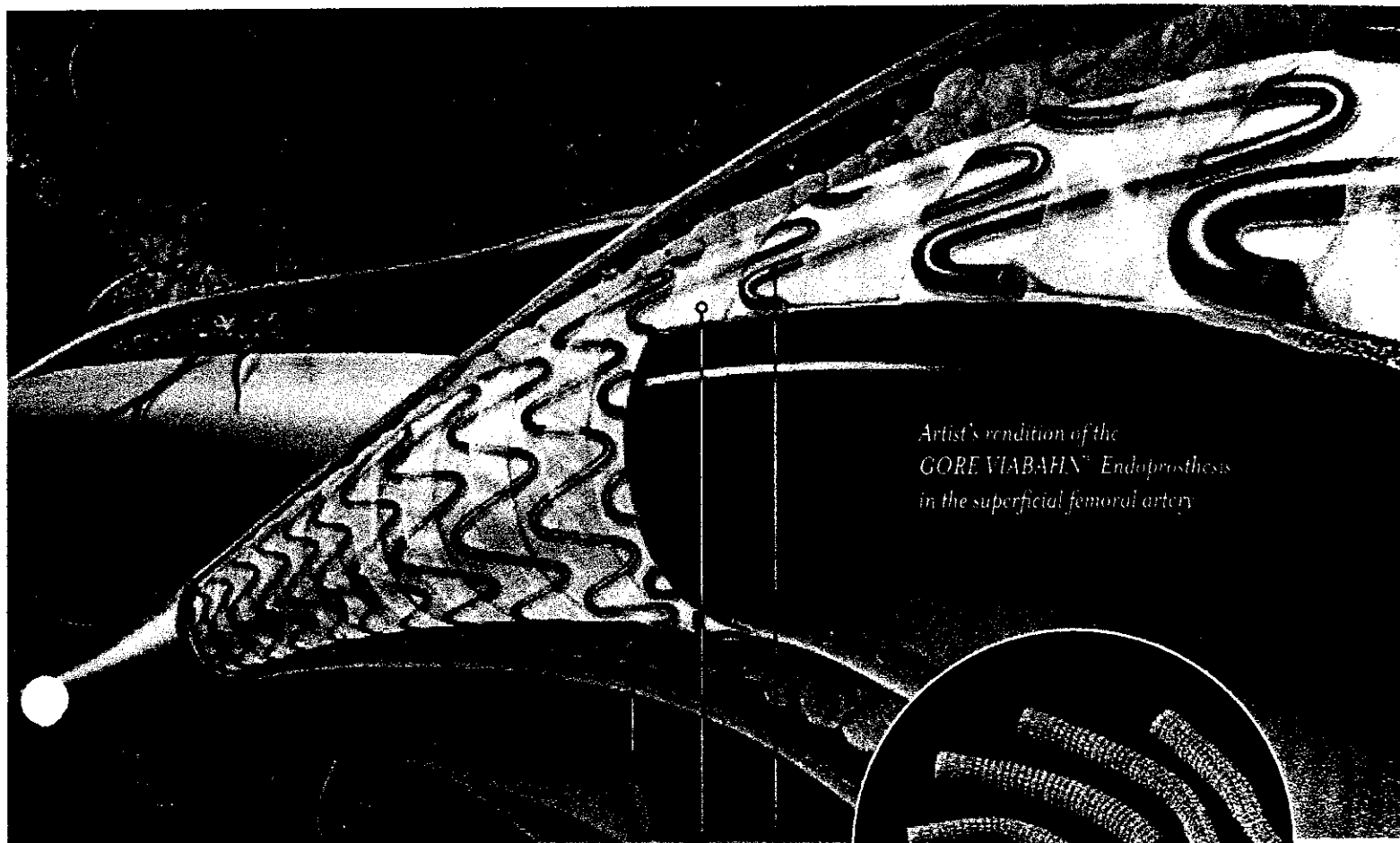


Figure 2

Plaque

ePTFE graft

Nitinol stent

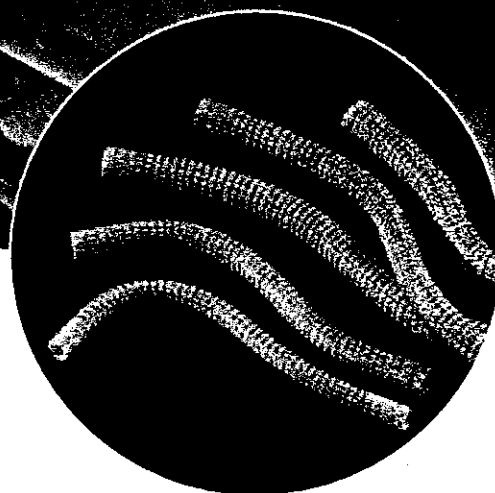


Figure 3

Photograph of several sizes of the  
GORE VIABAHN® Endoprosthesis

## *What is the GORE VIABAHN® Endoprosthesis?*

The GORE VIABAHN® Endoprosthesis is a very thin vascular graft that is supported by a metallic support structure known as a stent. The graft is made from fluoropolymers (expanded polytetrafluoroethylene or “ePTFE” and fluorinated ethylene propylene or “FEP”) materials, which have been used safely in vascular grafts for 30 years. The stent is made of a flexible, high-strength metal called Nitinol (see Figures 2 and 3).

Prior to implantation, the endoprosthesis is compressed on the end of a long, thin, tube-like device called a **delivery catheter** (see Figure 4). This allows the device to be inserted into your bloodstream through a small hole and guided to the diseased area of the blood vessel without open surgery. The diseased artery is then opened up by releasing the endoprosthesis from the **delivery catheter** inside the blood vessel, making a new path for the blood to flow.

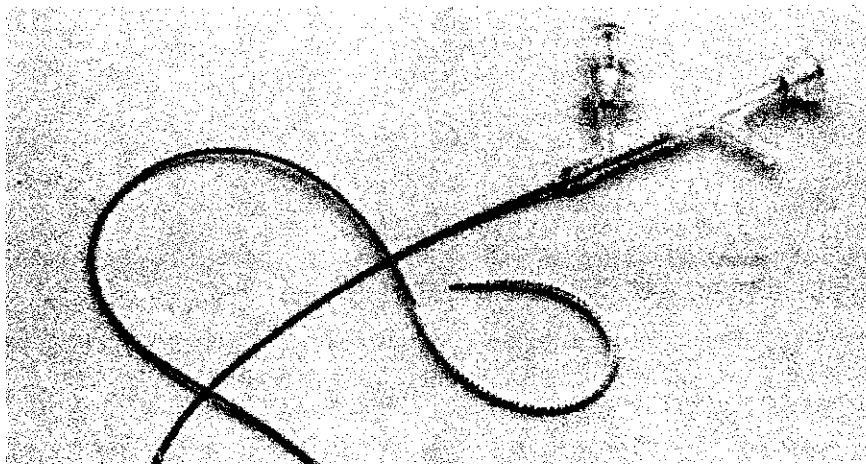


Figure 4

*GORE VIABAHN® Endoprosthesis compressed on a delivery catheter*

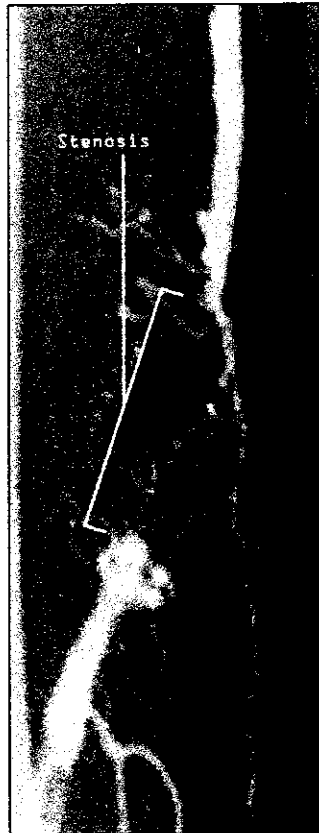


Figure 5a  
Pre-procedure

*Angiogram showing a section of the superficial femoral artery blocked with plaque.*

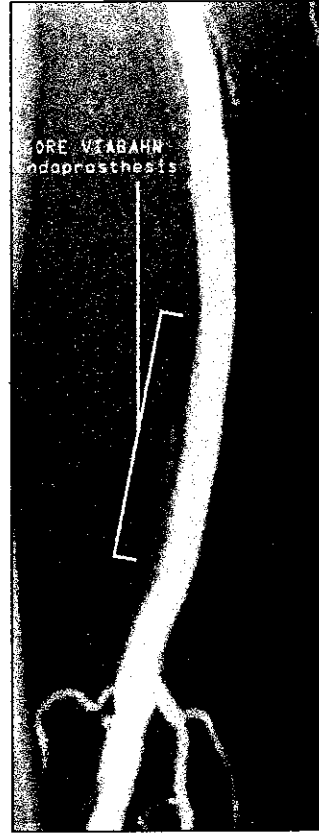


Figure 5b  
Post-procedure

*An angiogram with blood flowing through a GORE VIABAHN® Endoprosthesis in the superficial femoral artery.*

## *How is the GORE VIABAHN® Endoprosthesis Implanted?*

To treat your vascular disease, the GORE VIABAHN® Endoprosthesis is placed inside the blood vessel to create a new, disease-free channel for blood flow. The **endovascular graft** is implanted using **fluoroscopy** (real-time X-ray images) viewed on a TV monitor in these simple steps:

1. A **delivery catheter** is inserted into the **femoral artery** and carefully guided through the leg artery to the site of the blockage.
2. Once the **delivery catheter** reaches the diseased area, the **endovascular graft** is released from the **delivery catheter**.
3. The device self-expands to the diameter of the blood vessel that is being treated.  
The **endovascular graft** is designed to keep blood flow away from the diseased portion of the artery wall; at the same time it provides a new surface lining along the diseased portion of the artery wall.
4. The **delivery catheter** is withdrawn from the body.

At the end of the procedure, your doctor will check the position of the implanted device and also check the blood flow on a TV monitor using a technique called X-ray **angiography** (see Figures 5a and 5b).



## *What Are the Risks of the GORE VIABAHN® Endoprosthesis?*

Implantation of a GORE VIABAHN® Endoprosthesis may cause complications at the insertion site artery, or in the leg artery it is intended to treat. Complications that are related to the device may include but are not limited to:

- ▶ **Hematoma** (bruise)
- ▶ **Stenosis** (narrowing of the device)
- ▶ **Thrombosis** (blood clot in the artery or device)
- ▶ **Occlusion** (complete blockage of the blood flowing in the artery or device)
- ▶ **Distal embolism** (blood clot in the artery that has traveled down to the arteries in the lower leg or foot)
- ▶ **Vessel wall trauma and/or rupture**
- ▶ **Infection**
- ▶ **Inflammation**
- ▶ **Fever and/or pain in the absence of infection**
- ▶ **Device failure**
- ▶ **Allergic reaction to the x-ray dye or other procedural components**  
(including metals in the device)
- ▶ **Radiation injury**
- ▶ **X-Ray induced renal failure**

Be sure to discuss these risks and any other concerns you have with your physician.



### *What Follow-Up Examinations Should I Have?*

Your physician will schedule regular follow-up visits to check on the implanted device, such as at 1, 6, or 12 months following implantation, and then once a year thereafter. It is important that you go to all follow-up visits recommended by your doctor. During these visits, if the physician feels that there is a problem with the **endovascular graft** or that the disease has spread to other locations in your arteries, additional tests may be conducted.

### *When Should I Call My Doctor?*

The long-term safety and effectiveness of **endovascular repair** have not been established. **WARNING:** If your original symptoms return, or if you experience sudden pain in the treated leg, call your physician immediately. A return of symptoms can indicate either a failure of the endoprosthesis or a progression of the disease to other areas in the artery. In such cases, your doctor may recommend outpatient procedures and/or surgery. It is important to discuss with your doctor other potential symptoms or warning signs that indicate that the device is not working properly.

As with any surgery or medical procedure, there are potential complications with the treatment of **PVD**. Discuss the risks and benefits with your doctor, and refer to this brochure for basic information.

## *Glossary of Medical Terms*

### **Angiography/Angiogram**

A method whereby dye is injected into the bloodstream to view blood flow through the blood vessels under X-ray. Utilizes contrast (dye) and small radiation exposure. The resulting image is an angiogram.

### **Angioplasty**

Opening a blockage in a vessel by inflating a small balloon in the diseased area.

### **Atherosclerosis**

The build-up of plaque and fatty acids in the artery over time.

### **Contrast (dye)**

A drug injected into the vascular system to show blood flow through the blood vessels on the X-ray image.

### **CT Scan (Computed Tomography Scan)**

An imaging technique that creates very precise, thin, cross-sectional views of your abdomen and legs or concerned blood vessels. This technique often utilizes contrast (dye) and small radiation exposure. Also known as a CAT scan.

### **Delivery Catheter**

A long, thin, tube-like tool that assists in the positioning and delivering of an endovascular graft through the vascular system.

### **Distal Embolism**

Blood clot in the artery that has traveled down to the arteries in the lower leg or foot.

### **Endovascular Graft**

A synthetic graft implanted within a diseased vessel intended to support weakened vessel walls without the use of open surgery techniques. Endovascular grafts are delivered to the diseased blood vessel at a small size and then deployed or expanded to the size of the vessel in which it is placed.

### **ePTFE**

Expanded polytetrafluoroethylene, an inert and biocompatible polymer which can be used for medical devices.

### **Endovascular Repair**

Considered to be less invasive than open surgery, it involves the use of an endovascular graft to make a new path for blood to flow.

### **Endovascular Treatment**

The use of real time X-rays and guidewires to treat unhealthy arteries with small incisions in the femoral arteries.

### **Femoral Arteries**

Arteries located in each leg near the groin which carry blood to the femur or thigh region of each leg and the rest of the leg and foot.

### **Fluoroscopy**

A real time X-ray image that is viewed on a TV monitor and used with a C-arm during endovascular repair.

**Guidewire**

Long, flexible wire that is placed in an artery to track a delivery catheter and other endovascular accessories to implant an endovascular graft.

**Hematoma (bruise)**

Small blood vessels that tear or rupture under the skin leaving blood to leak and cause a black-and-blue color.

**IVUS (Intravascular Ultrasound)**

An ultrasound probe on a delivery catheter placed inside your arteries to see the vessel walls and measure diameters and lengths of your arteries.

**Lesion**

A diseased section of a blood vessel.

**MRI (Magnetic Resonance Imaging)**

A procedure using magnetic fields and radio waves to form an image of structures inside the body.

**Nitinol**

An inert, high-strength metal which is a mixture of nickel and titanium.

**Occlusion**

The blocking of an artery, causing normal blood flow to stop.

**Open Surgery**

An operation where an incision is made into the body to get access to a particular organ, for example, bypass surgery.

**Peripheral Arteries**

Arteries outside of the heart (coronary arteries) and aorta. For example, arteries in your arms or legs.

**PVD**

Peripheral vascular disease.

**Radiation**

A form of energy that allows your doctor to see blood vessel structures and other anatomy inside your body.

**Stenosis**

Narrowing or partial blockage of the artery or the inside of the endovascular graft.

**Stenting**

An endovascular repair with the placement of a small, metallic device in the diseased artery in an attempt to hold the artery open.

**Superficial Femoral Artery (SFA)**

Portion of the femoral artery in the thigh.

**Synthetic Graft**

A man-made material in tube form intended to replace diseased human vessels.

**Ultrasound**

An image created through the use of high-frequency sound waves.

## *Where Can I Get More Information?*

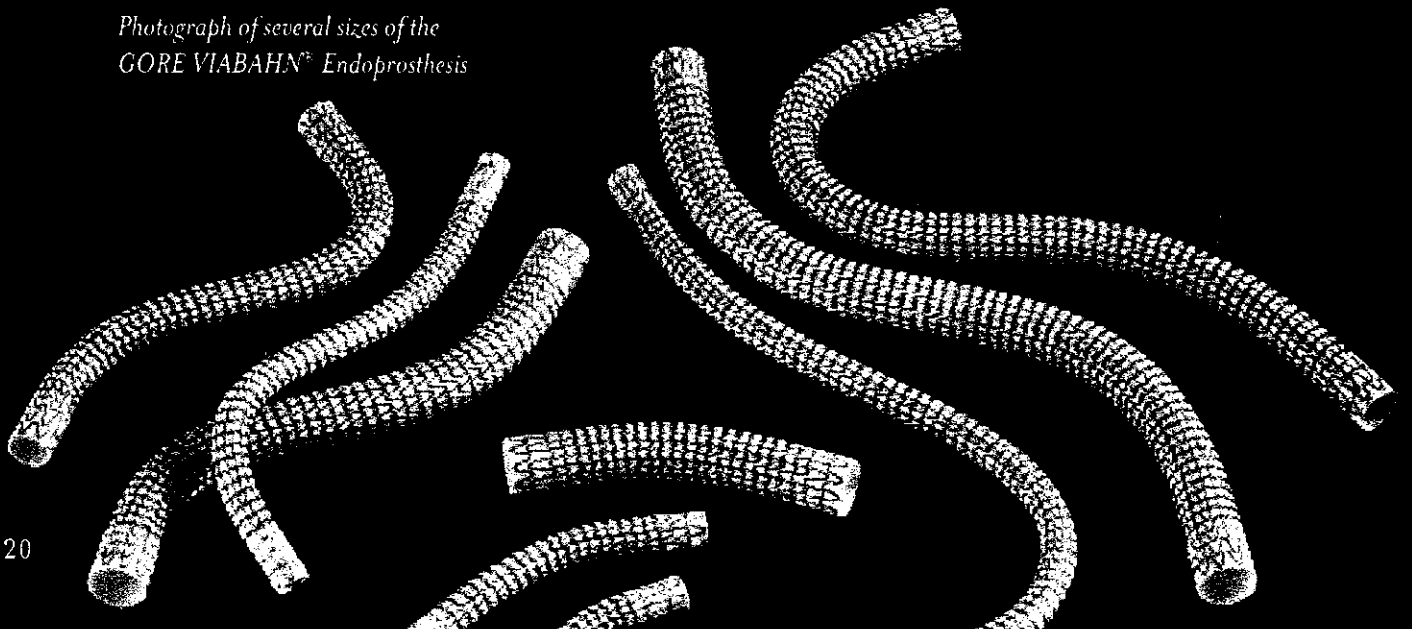
Society of Interventional Radiology  
[www.sirweb.org](http://www.sirweb.org)

US National Library of Medicine  
[www.medlineplus.gov](http://www.medlineplus.gov)

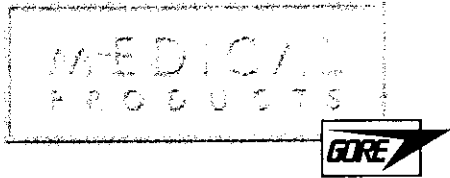
US Department of Health and Human Services  
Food and Drug Administration  
[www.fda.gov](http://www.fda.gov)

W. L. Gore & Associates, Inc.  
[www.goremedical.com](http://www.goremedical.com)

*Photograph of several sizes of the  
GORE VIABAHN® Endoprosthesis*



*Questions for My Doctor —*



**W. L. Gore & Associates, Inc.**  
Medical Products Division  
Flagstaff Arizona 86004

800 / 528-8763

[goremedical.com](http://goremedical.com)

GORE, VIABAHN®, and designs are trademarks of W. L. Gore & Associates.  
© 2005 W. L. Gore & Associates, Inc. AJ0060-EN1 MARCH 2005